

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

February 15, 2017

DP BARCODE: 436522

MRID(s): 469212-01, 470425-01, 500318-01,-02

SUBJECT: HM4100 Antimicrobial

REG. NO. OR FILE SYMBOL: 83019-1

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR **End-use Product [X]**

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number(s)</u>	<u>Active Ingredient(s):</u>
107401	27668-52-6	1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride

TEST LAB: N/A

SUBMITTER: Biosafe, Inc

GUIDELINE(S): 830.1550 - 830.1800; 830.6302 – 830.7950

COMMODITIES: Formulation

REVIEWER: Boris S. Yurchak

ORGANIZATION: AD/PSB/CTT

APPROVER: Karen P. Hicks

APPROVED DATE: 03/03/2017

COMMENT: This product is for non-food use

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. No. 83019-1
Product Name: HM4100 Antimicrobial
DP Barcode: 436522

TO: Jose Gayoso / Timothy Young
Regulatory Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P) 

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P) 

APPLICANT: Biosafe, Inc
Action code: (A676) Product Reregistration Decision
Due out date: February 1, 2017

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride	84.0
<u>Other Ingredient(s)</u>	<u>16.0</u>
TOTAL	100.0

BACKGROUND:

Scientific & Regulatory Consultants, Inc on behalf of Biosafe, Inc provided a package of documents to support the reregistration of product *HM4100 Antimicrobial*, EPA Reg. No. 83019-1. The registrant is requesting product chemistry review of the subject product.

The data package included:

1. Cover letter from the Registrant to EPA, dated 09/23/2016.
2. EPA Application Form 8570-1, dated 09/22/2016.
3. MRIDs as listed on the front page.
4. Approved basic CSF (pre and post-reaction), dated 08/02/2011.
5. Formulator's Exemption Statement, dated 09/22/2016.
6. Transmittal Document, dated 09/22/2016
7. Certification with Respect to Citation of Data, dated 09/22/2016.
8. Data Matrix, dated 09/22/2016.
9. Accepted label, stamped 09/08/2014.

FINDINGS:

1. EPA Reg. No. **83019-1** is an end-use product containing the active ingredient 1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride with a label claim nominal concentration of 84%, and other ingredients content of 16%. The product is in the form of a dry powder to be used to impart biostatic activity to a wide variety of substrates of interest. It is effective against mold, mildew and algae as a static agent. The product is produced by a non-integrated system.
2. A new basic CSF, that should be approved under the reregistration process, is not submitted.

CONCLUSION:

The currently submitted Data Package for reregistration of product EPA Reg. No. 83019-1 cannot be reviewed due to absence of a new CSF (Finding # 2).